1	UNITED STATES DISTRICT COURT					
2	EASTERN DISTRICT OF PENNSYLVANIA					
3						
4	UNITED STATES OF AMERICA : CRIMINAL DOCKET FOR					
5	: CASE NO. 13-605 -VS-					
6	JANSSEN PHARMACEUTICALS, :					
7	INC.					
8						
9	PHILADELPHIA, PA.					
10	NOVEMBER 7, 2013					
11	BEFORE HONORABLE TIMOTHY J. SAVAGE					
12	ARRAIGNMENT/GUILTY PLEA & SENTENCE					
13	APPEARANCES:					
14	FOR THE GOVERNMENT: U.S. ATTORNEY'S OFFICE					
15	BY: ALBERT S. GLENN, AUSA AND SCOTT M. CULLEN, AUSA					
16	615 CHESTNUT STREET, SUITE 1250 PHILADELPHIA, PA 19106					
17						
18	FOR THE DEFENDANT: MONTOMERY MCCRACKEN WALKER & RHOADS, LLP					
19	BY: RICHARD L. SCHEFF, ESQ. 123 SOUTH BROAD STREET					
20	PHILADELPHIA, PA 19109					
21	KING & SPALDING LLP BY: CHRISTOPHER A. WRAY, ESQ.					
22	1700 PENNSYLVANIA AVE, NW SUITE 200 WASHINGTON, DC 20006					
23	LYNN MCCLOSKEY, RPR					
24	OFFICIAL COURT REPORTER 1234 US COURTHOUSE					
25	601 MARKET STREET PHILADELPHIA, PA 19106 (856) 649-4774					

- 1 (PROCEEDINGS COMMENCED 9:00 A.M.)
- THE COURT: GOOD MORNING. PLEASE BE
- 3 SEATED.
- 4 ALL COUNSEL: GOOD MORNING, YOUR HONOR.
- 5 THE COURT: THIS IS THE MATTER OF THE
- 6 UNITED STATES VERSUS JANSSEN PHARMACEUTICALS,
- 7 INCORPORATED, CRIMINAL NUMBER 13-605.
- 8 ARE PARTIES READY TO PROCEED?
- 9 MR. GLENN: WE ARE, YOUR HONOR.
- 10 MR. SCHEFF: YES, YOUR HONOR.
- 11 THE COURT: ALL RIGHT. WHO WILL BE
- 12 STANDING IN FOR THE CORPORATE DEFENDANT?
- 13 MR. SCHEFF: YOUR HONOR, DEPUTY GENERAL
- 14 COUNSEL JOSEPH BRAUNREUTHER, WHO IS SEATED TO MY
- 15 RIGHT, WILL BE THE COMPANY REPRESENTATIVE.
- 16 MR. BRAUNREUTHER: GOOD MORNING, YOUR
- 17 HONOR.
- THE COURT: GOOD MORNING.
- MR. GLENN, I ASSUME YOU WILL BE TAKING
- 20 CARE OF IT FOR THE GOVERNMENT?
- 21 MR. GLENN: I WILL SPEAK FOR THE
- 22 GOVERNMENT, YES, YOUR HONOR. THANK YOU.
- THE COURT: DO YOU WANT TO INTRODUCE
- 24 YOUR CO-COUNSEL THERE?
- MR. GLENN: YES, YOUR HONOR. ALSO

- 1 REPRESENTING THE GOVERNMENT HERE THIS MORNING IS
- 2 ASSISTANT U.S. ATTORNEY SCOTT CULLEN. ALSO AT
- 3 COUNSEL TABLE ARE TWO OF THE CASE AGENTS, SPECIAL
- 4 AGENT JONELLE DAVENPORT WITH HHS IG'S OFFICE,
- 5 SPECIAL AGENT KISHARA GANT WITH THE DEFENSE CRIMINAL
- 6 INVESTIGATIVE SERVICE. ALSO IN THE AUDIENCE IS
- 7 ANOTHER ONE OF THE CASE AGENTS, CONTRACT AGENT
- 8 SAMUEL HENCK WITH THE FDA.
- 9 THE COURT: AND IT APPEARS HALF OF THE
- 10 U.S. ATTORNEY'S OFFICE?
- 11 MR. GLENN: YES. I CAN INTRODUCE THEM
- 12 AS WELL, IF YOU WOULD LIKE.
- 13 THE COURT: I NOTE MR. MEMEGER AND MR.
- 14 LAPPEN ARE HERE. THAT'S ENOUGH FOR YOU TO WORRY
- 15 ABOUT.
- 16 MR. SCHEFF, DO YOU WANT TO INTRODUCE
- 17 YOUR CO-COUNSEL?
- 18 MR. SCHEFF: YES, YOUR HONOR. MY
- 19 CO-COUNSEL IS CHRISTOPHER WRAY FROM THE LAW FIRM OF
- 20 KING & SPALDING WHO IS SEATED TO MR. BRAUNREUTHER'S
- 21 RIGHT. AND TO MR. WRAY'S RIGHT IS NORV MCANDREW WHO
- 22 IS ALSO INHOUSE COUNSEL WITH THE COMPANY.
- THE COURT: OKAY. MR. GRACE, DO YOU
- 24 WANT TO SWEAR IN THE CORPORATE REPRESENTATIVE,
- 25 PLEASE?

- THE DEPUTY CLERK: MR. BRAUNREUTHER,
- 2 PLEASE RAISE YOUR RIGHT HAND, SIR.
- 3 (CORPORATE REPRESENTATIVE, JOSEPH
- 4 BRAUNREUTHER, WAS SWORN.)
- 5 THE DEPUTY CLERK: PLEASE STATE YOUR
- 6 NAME FOR THE RECORD AND SPELL YOUR LAST NAME.
- 7 MR. BRAUNREUTHER: JOSEPH BRAUNREUTHER,
- B-R-A-U-N-R-E-U-T-H-E-R.
- 9 THE DEPUTY CLERK: THANK YOU, SIR. YOU
- 10 MAY BE SEATED.
- 11 BY THE COURT:
- 12 Q. SIR, YOU ARE HERE TO SPEAK ON
- BEHALF OF THE CORPORATION, IS THAT CORRECT?
- A. YES, YOUR HONOR.
- 15 Q. IS THAT PURSUANT TO A RESOLUTION
- 16 PASSED BY THE BOARD OF DIRECTORS?
- 17 A. IT IS, YOUR HONOR.
- 18 Q. WHAT WAS THE DATE OF THAT?
- 19 A. I HAVE AN EXCERPT THAT IS ATTACHED
- 20 TO THE SUBMISSION TO THE COURT. I DON'T KNOW
- 21 THAT IT HAS -- THE COPY WE HAVE WITH US, YOUR
- 22 HONOR -- EXCUSE ME, YOUR HONOR, WE DO IN FACT
- 23 HAVE IT. IT'S DATED OCTOBER 17, 2013.
- 24 Q. OKAY. AND THAT GIVES YOU THE
- 25 AUTHORITY TO SPEAK ON BEHALF OF THE CORPORATION?

- 1 A. IT DOES, YOUR HONOR.
- 2 O. AND TO ENTER INTO ANY AGREEMENTS?
- A. YES, IT DOES, YOUR HONOR.
- 4 Q. OKAY. I UNDERSTAND FROM MY PERUSAL
- 5 OF THE DOCUMENTS THAT YOUR KNOWLEDGE IN THIS
- 6 MATTER IS LIMITED TO WHAT IS INVOLVED IN THIS
- 7 CRIMINAL CHARGE, AND THAT IT DOES NOT RISE TO
- 8 THE LEVEL OF A 30(B)(6) WITNESS, AM I CORRECT?
- 9 A. THAT IS CORRECT, YOUR HONOR.
- 10 Q. ALL RIGHT. YOU MAY BE SEATED.
- 11 A. THANK YOU, YOUR HONOR.
- 12 Q. SIR, YOU UNDERSTAND THAT YOU ARE
- 13 NOW UNDER OATH?
- 14 A. YES, YOUR HONOR.
- 15 O. ALL RIGHT. AND THAT MEANS THAT YOU
- 16 HAVE TO ANSWER MY QUESTIONS TRUTHFULLY AND IF
- 17 YOU DO NOT, YOU WILL BE SUBJECT TO A CHARGE OF
- 18 PERJURY, DO YOU UNDERSTAND THAT?
- 19 A. YES, YOUR HONOR.
- 20 O. WHAT IS YOUR RELATIONSHIP TO THE
- 21 CORPORATE DEFENDANT IN THIS CASE?
- 22 A. YOUR HONOR, I AM HERE AS A
- 23 DESIGNATED REPRESENTATIVE PURSUANT TO THE
- 24 RESOLUTION. I AM A MEMBER OF THE JOHNSON AND
- 25 JOHNSON LAW DEPARTMENT. I AM NOT AN EMPLOYEE OF

- 1 JANSSEN.
- 2 O. OKAY. YOUR UNDERSTANDING IS THAT
- 3 THE BOARD OF DIRECTORS HAS BEEN FULLY INFORMED
- 4 OF ALL OF THE HAPPENINGS IN THIS CASE BY
- 5 PLAINTIFFS HERE TO THIS DATE?
- 6 A. YES, YOUR HONOR, THEY -- THE BOARD
- 7 OF DIRECTORS HAS AUTHORIZED ME TO ACT ON ITS
- 8 BEHALF BASED ON ITS UNDERSTANDING OF THE PLEA
- 9 AND THE PLEA AGREEMENT.
- 10 Q. OKAY. AND YOU PARTICIPATED IN THAT
- 11 PLEA AGREEMENT, IS THAT CORRECT, THAT IS THE
- 12 NEGOTIATION OF IT?
- A. YES, YOUR HONOR.
- 14 Q. AND YOU WERE INTIMATELY INVOLVED IN
- 15 THE CIVIL PROCEEDINGS IN THIS CASE AS WELL?
- 16 A. I AM FAMILIAR WITH THE CIVIL
- 17 PROCEEDINGS AS WELL, YOUR HONOR, AND THE
- 18 NEGOTIATIONS OF THE RESOLUTION OF THE CIVIL
- 19 PROCEEDING, CORRECT.
- Q. ALL RIGHT.
- 21 AND THE BOARD OF DIRECTORS HAS GIVEN
- 22 YOU THE AUTHORITY TO ENTER A PLEA ON BEHALF OF THE
- 23 CORPORATION TODAY?
- A. THAT IS CORRECT, YOUR HONOR.
- Q. AND THEY WERE FULLY INFORMED OF THE

- 1 CONSEQUENCES OF ENTERING INTO THIS PLEA?
- 2 A. PURSUANT TO THE RESOLUTION, THE
- 3 BOARD OF DIRECTORS HAS AUTHORIZED ME TO ENTER
- 4 THE PLEA AND IS AWARE OF THE RIGHTS THAT ARE
- 5 INVOLVED.
- 6 Q. THEY HAVE AN UNDERSTANDING THAT
- 7 THEY COULD FORCE THE GOVERNMENT TO CHARGE THEM
- 8 BY WAY OF INDICTMENT AND PROCEED TO A CRIMINAL
- 9 TRIAL?
- 10 A. I AM AWARE OF THAT, YOUR HONOR.
- 11 Q. AND YOU HAVE THE AUTHORITY TO --
- 12 A. I HAVE THE AUTHORITY TO ENTER THE
- 13 PLEA.
- 14 THE COURT: DO THE PARTIES AGREE
- THE TOTAL OFFENSE LEVEL IS A 6 AND THAT WITH
- 16 ACCEPTANCE OF RESPONSIBILITY, THAT THAT IS
- 17 REDUCED TO 4?
- MR. GLENN: YES, YOUR HONOR.
- MR. SCHEFF: YES, YOUR HONOR.
- 20 THE COURT: AND THE CRIMINAL HISTORY
- 21 CATEGORY IS A 1, CORRECT?
- MR. SCHEFF: THAT IS CORRECT, YOUR
- HONOR.
- MR. GLENN: CORRECT.
- THE COURT: DO THE PARTIES AGREE THAT

- 1 UNDER THAT TOTAL OFFENSE LEVEL AND CRIMINAL HISTORY
- 2 CATEGORY THAT THE SENTENCING GUIDELINES PROVIDE FOR
- 3 A PROBATIONARY RANGE OF NO MORE THAN THREE YEARS?
- 4 MR. GLENN: THAT'S CORRECT, YOUR HONOR.
- 5 MR. SCHEFF: YES, YOUR HONOR.
- 6 THE COURT: OKAY. LET ME HEAR FROM THE
- 7 GOVERNMENT.
- 8 MR. GLENN: WITH RESPECT TO THE --
- 9 WHICH PART OF THE PLEA PROCEEDINGS?
- 10 THE COURT: THE FACTUAL BASIS, PLEASE.
- 11 MR. GLENN: THE FACTUAL BASIS. YES,
- 12 YOUR HONOR.
- 13 THE COURT: FIRST, RECITE WHAT THE
- 14 ELEMENTS OF THE OFFENSE ARE.
- MR. GLENN: SURE. THE CHARGE HERE,
- 16 YOUR HONOR, IN COUNT 1 OF THE INFORMATION IS
- 17 INTRODUCTION OF A MISBRANDED DRUG INTO INTERSTATE
- 18 COMMERCE IN VIOLATION OF 21 U.S.C. SECTIONS 331(A)
- AND 333(A)(1). THE ELEMENTS OF THIS OFFENSE ARE
- 20 FIRST, THAT RISPERDAL IS A DRUG; SECONDLY, THAT
- 21 RISPERDAL WAS MISBRANDED AND THAT IT LACKED ADEQUATE
- 22 DIRECTIONS FOR THE USE INTENDED BY JANSSEN; AND
- 23 THIRD, THAT JANSSEN CAUSED RISPERDAL WHILE
- 24 MISBRANDED TO BE INTRODUCED INTO INTERSTATE
- 25 COMMERCE.

- 1 THE COURT: MR. SCHEFF, HAVE YOU
- 2 DISCUSSED THE ELEMENTS OF THE OFFENSE WITH YOUR
- 3 CLIENT?
- 4 MR. SCHEFF: I HAVE, YOUR HONOR.
- THE COURT: AND EXPLAINED TO THEM WHAT
- 6 THE GOVERNMENT WOULD HAVE TO PROVE?
- 7 MR. SCHEFF: I HAVE, YOUR HONOR.
- 8 THE COURT: IS THAT CORRECT, SIR?
- 9 THE WITNESS: YES, YOUR HONOR.
- 10 THE COURT: DO YOU HAVE ANY QUESTIONS
- 11 ABOUT THAT?
- 12 THE WITNESS: NO, YOUR HONOR.
- 13 THE COURT: ALL RIGHT. MR. GLENN,
- 14 WOULD YOU KINDLY RECITE FOR US WHAT THE FACTUAL
- 15 BASIS FOR THE PLEA IS.
- 16 MR. GLENN: YES, YOUR HONOR. FIRST
- 17 THOUGH I AM GOING TO REFER TO THAT WHICH THE COMPANY
- 18 HAS STIPULATED TO IN THE PLEA AGREEMENT. WE HAVE
- 19 AGREED TO THE FOLLOWING FACTS, WHICH WE URGE THE
- 20 COURT TO ACCEPT AS A FACTUAL BASIS. THAT JANSSEN
- 21 MARKETED RISPERDAL THROUGH JANSSEN PHARMACEUTICA,
- 22 INC., A PREDECESSOR COMPANY TO JANSSEN, AND THAT
- 23 WOULD BE FOR THE PERIOD OF TIME CHARGED IN THE
- 24 INFORMATION, FROM MARCH 3, 2002 TO DECEMBER 31,
- 25 2003. RISPERDAL WAS A DRUG WITHIN THE MEANING OF 21

- 1 U.S.C. SECTION 321(G)(1).
- 2 SHIPMENTS OF A DRUG IN INTERSTATE
- 3 COMMERCE MUST BE ACCOMPANIED BY LABELING BEARING
- 4 ADEQUATE DIRECTIONS FOR USE FOR EACH OF THE DRUG'S
- 5 INTENDED USES. IN DECEMBER 1993, THE U.S. FOOD AND
- 6 DRUG ADMINISTRATION APPROVED RISPERDAL FOR THE
- 7 MANAGEMENT OF THE MANIFESTATIONS OF PSYCHOTIC
- 8 DISORDERS. IN MARCH OF 2002, THE FDA APPROVED A
- 9 CHANGE IN THE INDICATIONS FOR RISPERDAL, APPROVING
- 10 IT FOR THE TREATMENT OF SCHIZOPHRENIA INSTEAD OF THE
- 11 MANAGEMENT OF MANIFESTATIONS OF PSYCHIC DISORDERS.
- 12 IN DECEMBER OF 2003, THE FDA ADDITIONALLY APPROVED
- 13 RISPERDAL FOR THE SHORT-TERM TREATMENT OF ACUTE
- 14 MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR 1
- 15 DISORDER FOR ADULTS.
- 16 BETWEEN MARCH 3RD OF 2002 AND
- 17 DECEMBER 31ST OF 2003, JANSSEN THROUGH JANSSEN
- 18 PHARMACEUTICA'S ELDER CARE SALES FORCE PROMOTED
- 19 RISPERDAL TO HEALTHCARE PROVIDERS FOR TREATMENT OF
- 20 PSYCHOTIC SYMPTOMS AND ASSOCIATED BEHAVIORAL
- 21 DISTURBANCES EXHIBITED BY ELDERLY NON-SCHIZOPHRENIC
- 22 DEMENTIA PATIENTS. JANSSEN'S PROMOTION OF RISPERDAL
- FOR THESE ADDITIONAL INTENDED USES CAUSED RISPERDAL
- 24 TO BE MISBRANDED UNDER SECTION 21 U.S.C. SECTION --
- 352(F)(1) BECAUSE RISPERDAL'S LABELING DID NOT BEAR

- 1 ADEQUATE DIRECTIONS FOR THESE INTENDED USES.
- 2 BETWEEN MARCH 3RD OF 2002 AND DECEMBER 31ST OF 2003,
- 3 JANSSEN CAUSED SHIPMENTS OF RISPERDAL TO BE
- 4 INTRODUCED INTO INTERSTATE COMMERCE AND THESE
- 5 SHIPMENTS CONSTITUTED MISBRANDED DRUGS DUE TO THE
- 6 CONDUCT DESCRIBED ABOVE.
- 7 IN ADDITION, YOUR HONOR, WE WOULD SHOW
- 8 THAT JANSSEN PROMOTED AND SOLD RISPERDAL WITHIN THE
- 9 EASTERN DISTRICT OF PENNSYLVANIA.
- 10 BY THE COURT:
- 11 O. BEFORE I ASK YOU IF THAT'S WHAT
- 12 HAPPENED AND IF JANSSEN DID WHAT THE GOVERNMENT
- 13 SAID IT DID, I WANT TO MAKE SURE THAT YOU
- 14 UNDERSTAND ON THE RECORD, WHICH I AM SURE YOU
- 15 HAVE EXPLAINED TO JANSSEN, THAT RIGHT NOW THE
- 16 DEFENDANT IS PRESUMED INNOCENT AND THE
- 17 GOVERNMENT WOULD HAVE TO PROVE ALL OF THE FACTS
- 18 SET FORTH IN THAT AGREEMENT TO ESTABLISH THE
- 19 ELEMENTS BEYOND A REASONABLE DOUBT AND THAT YOU
- 20 COULD BRING PRETRIAL MOTIONS CHALLENGING THE WAY
- 21 THE GOVERNMENT CAME INTO POSSESSION OF CERTAIN
- 22 EVIDENCE WHICH IT INTENDS TO USE AGAINST JANSSEN
- 23 IF IT WERE TO GO TO TRIAL AND YOU COULD DO THAT
- 24 BEFORE TRIAL.
- 25 AND THAT JANSSEN WOULD BE ENTITLED

- 1 TO A JURY TRIAL, THAT IS TO HAVE THE CASE
- 2 DECIDED BY 12 PERSONS WHERE THE VERDICT WOULD
- 3 HAVE TO BE UNANIMOUS. OTHERWISE, JANSSEN COULD
- 4 BE FOUND GUILTY. THAT THE GOVERNMENT WOULD HAVE
- 5 TO PROVE ITS CASE BY PRESENTING EVIDENCE THROUGH
- THE MOUTHS OF THE WITNESSES WHO WOULD TESTIFY
- 7 HERE FROM THE WITNESS STAND AND JANSSEN'S
- 8 ATTORNEY WOULD HAVE THE OPPORTUNITY TO
- 9 CROSS-EXAMINE THOSE WITNESSES, AND THAT JANSSEN
- 10 COULD PRESENT ITS OWN WITNESSES.
- 11 ALSO, IF JANSSEN WANTED TO BRING IN
- 12 WITNESSES WHO REFUSED OR WERE RELUCTANT TO COME
- 13 IN, JANSSEN COULD REQUEST THE COURT TO ISSUE A
- 14 SUBPOENA REQUIRING THEM TO COME IN. JANSSEN
- 15 COULD ALSO PRESENT SOMEONE TO TESTIFY ON BEHALF
- 16 OF THE CORPORATION AND TELL THE JURY WHAT IT
- 17 WANTED TO, BUT DOES NOT HAVE TO PRESENT ANY
- 18 EVIDENCE OR ANY WITNESSES WHATSOEVER. AND NO
- 19 COMMENT COULD BE MADE ABOUT THAT BY ANYBODY NOR
- 20 COULD THE GOVERNMENT USE IT AGAINST YOU. IN
- 21 FACT, I WOULD TELL THE JURY THAT IT COULD
- 22 NOT HOLD IT AGAINST JANSSEN IF NO ONE TESTIFIED
- ON BEHALF OF JANSSEN OR THAT NO EVIDENCE WAS
- 24 PRESENTED BY JANSSEN.
- 25 AND YOU WOULD ALSO HAVE THE RIGHT

- 1 TO TAKE AN APPEAL FROM THE VERDICT OF GUILTY
- 2 WHICH IF YOU WERE SUCCESSFUL IN THE 3RD CIRCUIT
- 3 COURT OF APPEALS, THE CASE COULD BE REVERSED,
- 4 THAT IS THAT THE COURT COULD ORDER A NEW TRIAL,
- 5 MODIFY THE FINDING OF GUILT OR FIND THAT THE
- 6 GOVERNMENT HAS NOT PROVEN ANY CASE.
- 7 IN THIS AGREEMENT, JANSSEN HAS
- 8 AGREED THAT IT WILL NOT TAKE ANY APPEAL FROM THE
- 9 SENTENCE TO BE IMPOSED IN THIS CASE PURSUANT TO
- 10 THE AGREEMENT OF THE PARTIES. THAT MEANS YOU
- 11 CANNOT TAKE A DIRECT APPEAL IN THE 3RD CIRCUIT
- 12 COURT OF APPEALS, NOR COULD YOU FILE COLLATERAL
- 13 CHALLENGE UNDER SECTION 2255, IN A MOTION TO SET
- 14 ASIDE OR VACATE THE JUDGMENT, THE SENTENCE. DO
- 15 YOU UNDERSTAND THAT?
- A. YES, YOUR HONOR.
- 17 O. DO YOU UNDERSTAND ALL OF THOSE
- 18 RIGHTS ON BEHALF OF THE CORPORATION?
- 19 A. I DO, YOUR HONOR.
- 20 O. AND THEY WERE DISCUSSED WITH THE
- 21 DECISION MAKERS AT THE CORPORATE DEFENDANT'S
- 22 HEADQUARTERS?
- 23 A. I AM AUTHORIZED PURSUANT TO THE
- 24 RESOLUTION TO ENTER THE PLEA WITH FULL KNOWLEDGE
- 25 OF THE CIRCUMSTANCES THAT THE COURT JUST

- 1 DESCRIBED.
- 2 Q. AND YOU DO SO?
- 3 A. I DO.
- 4 Q. NOW THAT YOU KNOW WHAT THOSE RIGHTS
- 5 ARE, WHICH I AM SURE YOU DID, HAVING BEEN A
- 6 FORMER ASSISTANT UNITED STATES ATTORNEY.
- 7 A. YES, YOUR HONOR.
- 8 Q. IS JANSSEN GIVING UP THOSE RIGHTS?
- 9 A. YES, YOUR HONOR.
- 10 Q. AND INTENDS TO KEEP THIS AGREEMENT
- 11 AND ENTER INTO THIS PLEA?
- 12 A. IT DOES, YOUR HONOR.
- 13 Q. ALL RIGHT. HAVING GIVEN UP THOSE
- 14 RIGHTS, NOW I AM GOING TO ASK YOU, WHAT MR.
- 15 GLENN SAID JANSSEN DID AND WHAT HAPPENED, ALL
- 16 RIGHT, I WANT YOU TO RECALL WHAT HE SAID.
- 17 A. YES, YOUR HONOR.
- 18 Q. IS THAT WHAT HAPPENED?
- 19 A. THAT'S -- PURSUANT TO THE
- 20 RESOLUTION AND THE PLEA AGREEMENT ON BEHALF OF
- 21 THE COMPANY, WE DO AGREE TO ENTER A GUILTY PLEA
- 22 PURSUANT TO THE FACTUAL BASIS THAT MR. GLENN
- OUTLINED, WHICH FOLLOWED VERY DELIBERATELY AND
- 24 ACCURATELY THE PLEA AGREEMENT ITSELF AND THE
- 25 STIPULATED FACTS CONTAINED IN THE PLEA

- 1 AGREEMENT.
- 2 Q. SO THAT'S WHAT HAPPENED?
- 3 A. YES, YOUR HONOR. AS YOU POINTED
- 4 OUT EARLIER, I DON'T HAVE PERSONAL KNOWLEDGE OF
- 5 THE FACTS. BUT I DO HAVE AUTHORITY TO ENTER THE
- 6 PLEA BASED ON THOSE FACTS, AND THE COMPANY,
- 7 JANSSEN, IS ACKNOWLEDGING GUILT BASED ON THOSE
- 8 FACTS.
- 9 Q. THAT JANSSEN DID WHAT THE
- 10 GOVERNMENT SAID IT DID?
- 11 A. YES, YOUR HONOR.
- 12 Q. ALL RIGHT. ARE THERE ANY QUESTIONS
- 13 YOU WANT TO ASK?
- A. NO, YOUR HONOR.
- THE COURT: DO THE PARTIES AGREE --
- 16 WELL, WHY DON'T YOU DO THIS, MR. GLENN. WHY
- 17 DON'T YOU SET FORTH THE TERMS OF THE AGREEMENT.
- MR. GLENN: YES, YOUR HONOR. WE HAVE
- 19 ENTERED INTO AN AGREEMENT WITH THE DEFENDANTS, YOUR
- 20 HONOR, THAT HAS BEEN SUMMARIZED IN THE AGREEMENT.
- 21 JANSSEN WILL PLEAD GUILTY TO COUNT 1 OF THE
- 22 INFORMATION. THE AGREEMENT IS MADE UNDER RULE
- 23 11(C)(1)(C) AND THE PARTIES AGREE THAT THE
- 24 APPROPRIATE SENTENCE IS A FINE OF \$334 MILLION, A
- 25 FORFEITURE JUDGMENT OF \$66 MILLION AS SUBSTITUTE

- 1 ASSETS, AND A SPECIAL ASSESSMENT OF \$125. JANSSEN
- 2 AGREES TO PAY THESE PENALTIES WITHIN 10 BUSINESS
- 3 DAYS FROM THE DATE OF SENTENCING.
- 4 THE PARTIES AGREE THAT THE MISBRANDED
- 5 DRUGS ARE NO LONGER AVAILABLE. BECAUSE JANSSEN IS
- 6 UNDER A CORPORATE INTEGRITY AGREEMENT, JANSSEN WILL
- 7 NOT BE PLACED ON PROBATION. JANSSEN HAS ALSO
- 8 REACHED A SETTLEMENT IN A CIVIL CASE INVOLVING
- 9 RISPERDAL. JANSSEN WAIVES DEFENSES UNDER THE DOUBLE
- 10 JEOPARDY AND EXCESSIVE FINES CLAUSE OF THE EIGHTH
- 11 AMENDMENT. THE PARTIES AGREE THAT THIS CASE DOES
- 12 NOT INCLUDE A RESTITUTION ORDER. JANSSEN WAIVES ANY
- 13 CLAIM UNDER THE HYDE AMENDMENT.
- 14 THE INTENT OF THE PLEA AGREEMENT IS
- 15 THAT JANSSEN AS EXISTED ON JULY 6, 2011 IS THE
- 16 ENTITY WHICH IS PLEADING GUILTY. JANSSEN
- 17 UNDERSTANDS THE MAXIMUM PENALTIES FOR THE OFFENSE
- 18 CHARGED. THE PARTIES AGREE THAT THE AGREED-UPON
- 19 FINE HERE IS BELOW THE STATUTORY MAXIMUM AUTHORIZED
- 20 BY SECTION 3571(D). PARAGRAPH EIGHT OF THE PLEA
- 21 AGREEMENT, YOUR HONOR, ARE THE STIPULATIONS WHICH I
- JUST READ AS THE FACTUAL BASIS. JANSSEN UNDERSTANDS
- 23 THAT THE UNITED STATES CONTENDS THAT THE SCOPE OF
- 24 JANSSEN'S OFF-LABEL PROMOTION WAS BROADER THAN THAT
- 25 TO WHICH IT IS STIPULATED HERE.

1	JANSSEN HAS AGREED TO BE PLACED UNDER A
2	CORPORATE INTEGRITY AGREEMENT WITH THE HHS INSPECTOR
3	GENERAL. JANSSEN WAIVES ALL DEFENSES UNDER THE
4	CONSTITUTION OR SPEEDY TRIAL ACT AND ANY APPLICABLE
5	STATUTES OF LIMITATIONS AS DESCRIBED IN THIS
6	PARAGRAPH. JANSSEN AGREES THAT THE CURRENT
7	PROSECUTION IS TIMELY. THE AGREEMENT PROVIDES FOR
8	FURTHER TIME IF THE AGREEMENT IS NOT CARRIED OUT.
9	THE UNITED STATES WILL NOT BRING ANY
10	OTHER CRIMINAL CHARGES AGAINST JANSSEN OR RELATED
11	COMPANIES FOR CERTAIN CONDUCT AS SET FORTH IN THE
12	PLEA AGREEMENT. JANSSEN UNDERSTANDS THAT THIS
13	GUILTY PLEA DOES NOT BIND ANY OTHER GOVERNMENT
14	AGENCY OR ANY COMPONENT OF THE DEPARTMENT OF JUSTICE
15	EXCEPT AS SPECIFIED IN THE AGREEMENT. THE
16	GOVERNMENT TAKES NO POSITION ON THE TAX TREATMENT OF
17	ANY MATTERS RELATED TO THIS CASE.
18	JANSSEN WAIVES ALL RIGHTS TO APPEAL OR
19	COLLATERALLY ATTACK THE CONVICTION, SENTENCE OR ANY
20	OTHER MATTER RELATED TO THIS PROSECUTION. JANSSEN
21	WAIVES ALL RIGHTS WHETHER ASSERTED DIRECTLY OR BY A
22	REPRESENTATIVE TO REQUEST OR RECEIVE ANY RECORDS
23	PERTAINING TO THE INVESTIGATION OR PROSECUTION OF
24	THIS CASE, INCLUDING WITHOUT LIMITATION ANY RECORDS
25	THAT MIGHT BE SOUGHT UNDER THE FREEDOM OF

- 1 INFORMATION ACT OR THE PRIVACY ACT.
- 2 JANSSEN IS SATISFIED WITH THE LEGAL
- 3 REPRESENTATION PROVIDED BY ITS LAWYERS. JANSSEN AND
- 4 ITS LAWYERS HAVE FULLY DISCUSSED THIS GUILTY PLEA
- 5 AGREEMENT. JANSSEN IS AGREEING TO PLEAD GUILTY
- 6 BECAUSE JANSSEN ADMITS THAT IT IS GUILTY OF THE
- 7 OFFENSE DESCRIBED IN PARAGRAPH ONE. JANSSEN WILL
- 8 ACKNOWLEDGE ACCEPTANCE OF THIS GUILTY PLEA AGREEMENT
- 9 BY THE SIGNATURE OF ITS COUNSEL AND OF AN AUTHORIZED
- 10 CORPORATE OFFICER AND WILL PROVIDE DOCUMENTATION OF
- 11 THE AUTHORITY TO PLEAD GUILTY.
- THE PARTIES AGREE TO WAIVE THE
- 13 PRESENTENCE INVESTIGATION AND REPORT PURSUANT TO
- 14 RULE 32(C)(1) AND WILL JOINTLY REQUEST THAT JANSSEN
- 15 BE SENTENCED AT THE TIME THE GUILTY PLEA IS ENTERED
- 16 AND ACCEPTED BY THE COURT.
- 17 IT IS AGREED THAT THE GUILTY PLEA
- AGREEMENT CONTAINS NO ADDITIONAL PROMISES,
- 19 AGREEMENTS OR UNDERSTANDINGS OTHER THAN THOSE SET
- 20 FORTH IN THIS WRITTEN GUILTY PLEA AGREEMENT AND THAT
- 21 NO ADDITIONAL PROMISES, AGREEMENTS OR UNDERSTANDINGS
- 22 WILL BE ENTERED INTO UNLESS IN WRITING AND SIGNED BY
- 23 ALL PARTIES.
- 24 THAT SUMMARIZES THE PLEA AGREEMENT,
- 25 YOUR HONOR.

- 1 THE COURT: MR. SCHEFF, THAT WAS AN
- 2 AGREEMENT THAT WAS NEGOTIATED BETWEEN THE PARTIES
- 3 AFTER EXTENSIVE DISCUSSION, IS THAT CORRECT?
- 4 MR. SCHEFF: THAT IS CORRECT, YOUR
- 5 HONOR.
- THE COURT: HOW LONG WERE THE
- 7 NEGOTIATIONS?
- 8 MR. SCHEFF: NEGOTIATIONS OVER THE
- 9 CRIMINAL PLEA EXTENDED OVER A ONE-YEAR PERIOD OF
- 10 TIME, YOUR HONOR.
- 11 THE COURT: AND HAVE YOU THOROUGHLY
- 12 GONE OVER THAT AGREEMENT WITH THE DEFENDANT
- 13 CORPORATION?
- 14 MR. SCHEFF: I HAVE, YOUR HONOR.
- THE COURT: HAS HE?
- 16 THE WITNESS: YES, YOUR HONOR.
- 17 THE COURT: AND YOU -- WITH THOSE WHO
- 18 ARE RESPONSIBLE FOR MAKING THE DECISIONS AT JANSSEN,
- 19 DID YOU GO OVER IT WITH THEM?
- 20 THE WITNESS: WE ARE AUTHORIZED TO
- 21 ENTER THE PLEA AGREEMENT ON BEHALF OF JANSSEN WITH
- JANSSEN'S KNOWLEDGE OF THE TERMS AND THE AGREEMENT
- 23 AND JANSSEN AGREES TO PLEAD GUILTY.
- 24 THE COURT: THIS IS A GIVE AND TAKE?
- THE WITNESS: JANSSEN -- YOUR HONOR, I

- 1 DON'T WANT TO GET INTO THE PROCEEDINGS WITH JANSSEN
- 2 BECAUSE I AM IN THE LAW DEPARTMENT. I WAS
- 3 AUTHORIZED TO GO FORWARD ON THIS. I DON'T WANT IT
- 4 MISUNDERSTOOD. I DID NOT MAKE PERSONAL
- 5 REPRESENTATION.
- THE COURT: I UNDERSTAND. I DON'T WANT
- 7 TO GET IN ATTORNEY/CLIENT COMMUNICATION.
- THE WITNESS: YES, YOUR HONOR.
- 9 THE COURT: I JUST WANT TO MAKE SURE
- 10 THAT THEY THOROUGHLY UNDERSTOOD THE TERMS OF THIS
- 11 AGREEMENT AND THE CONSEQUENCES.
- 12 THE WITNESS: YES, YOUR HONOR.
- THE COURT: AND YOU EXPLAINED IT?
- 14 THE WITNESS: YES, YOUR HONOR.
- THE COURT: AND THEY ACKNOWLEDGED THAT
- 16 THEY UNDERSTOOD IT?
- 17 THE WITNESS: THE CORPORATION
- 18 UNDERSTANDS IT AND IT HAS BEEN EXPLAINED TO THEM.
- 19 THE COURT: THAT'S WHAT I WANT TO KNOW.
- 20 ARE THERE ANY CONDITIONS, ANY TERMS,
- 21 OTHER THAN WHAT ARE CONTAINED IN THE WRITTEN SIGNED
- 22 PLEA AGREEMENT AND AS HAS BEEN DISCLOSED HERE TODAY?
- THE WITNESS: NO, YOUR HONOR.
- 24 THE COURT: SO THAT'S THE ENTIRE --
- 25 THE WITNESS: THAT'S THE ENTIRE

- 1 AGREEMENT, YOUR HONOR.
- THE COURT: ALL RIGHT. ARE COUNSEL
- 3 SATISFIED THAT THERE IS A FACTUAL BASIS FOR THE
- 4 PLEA, THAT THE PLEA IS VOLUNTARY AND THAT IT'S NOT
- 5 BASED ON ANY TERMS OR CONDITIONS OTHER THAN THOSE
- 6 THAT ARE SET FORTH IN THE WRITTEN SIGNED PLEA
- 7 AGREEMENT AND AS HAS BEEN DISCLOSED HERE TODAY AND
- 8 THAT THE GUILTY PLEA IS BEING MADE WITH A FULL
- 9 UNDERSTANDING BY THE DEFENDANT OF THE NATURE OF THE
- 10 CHARGE, THE MAXIMUM POSSIBLE PENALTY AND THE
- 11 DEFENDANT'S LEGAL RIGHTS TO PURSUE A TRIAL?
- MR. GLENN: WE ARE, YOUR HONOR,
- 13 ALTHOUGH AT SOME POINT WILL THE COURT ASK US TO PUT
- 14 THE MAXIMUM PENALTIES ON THE RECORD?
- THE COURT: I THINK YOU STATED THEM,
- 16 DIDN'T YOU?
- 17 MR. GLENN: I THINK I DID NOT. AND I
- 18 CAN DO THAT --
- 19 THE COURT: I THOUGHT YOU DID IN YOUR
- 20 RECITATION, BUT GO AHEAD.
- 21 MR. GLENN: THE MAXIMUM PENALTY FOR
- 22 THIS CHARGE IN THE INFORMATION, YOUR HONOR, IS A
- 23 MAXIMUM FINE OF \$200,000 OR TWICE THE GROSS GAIN OR
- 24 GROSS LOSS, WHICHEVER IS GREATER. A SPECIAL
- 25 ASSESSMENT OF \$125, A 5-YEAR TERM OF COURT

- 1 SUPERVISION. IN ADDITION, FORFEITURE MAY BE
- ORDERED. THOSE ARE THE POSSIBLE PENALTIES IN THIS
- 3 CASE AND FORFEITURE HAS BEEN AGREED TO AS
- 4 \$66 MILLION.
- 5 THE COURT: AGREED?
- 6 MR. SCHEFF: YES, YOUR HONOR.
- 7 MR. GLENN: AND WITH THAT, WE AGREE
- 8 THAT THE PLEA IS BEING ENTERED VOLUNTARILY AS YOU
- 9 PREVIOUSLY ASKED US.
- 10 THE COURT: ALL RIGHT. I FIND THAT
- 11 THIS PLEA IS BEING MADE KNOWINGLY AND VOLUNTARILY
- 12 AND NOT THE RESULT OF ANY PROMISES OR CONDITIONS
- 13 OTHER THAN THOSE THAT ARE SET FORTH IN THE WRITTEN
- 14 SIGNED PLEA AGREEMENT AND HAS BEEN DISCLOSED HERE IN
- OPEN COURT, AND THAT IT IS SUPPORTED BY AN
- 16 INDEPENDENT BASIS IN FACT OF EACH OF THE ESSENTIAL
- 17 ELEMENTS OF THE VIOLATION CHARGED.
- 18 I FURTHER FIND THAT THE DEFENDANT WAS
- 19 REPRESENTED, UNDERSTANDS THE CHARGE, THE
- 20 CORPORATION'S LEGAL RIGHTS AND MAXIMUM POSSIBLE
- 21 PENALTY AND IT FURTHER UNDERSTANDS THAT IT IS GIVING
- 22 UP ITS RIGHT TO GO TO TRIAL.
- DO YOU NOW WISH TO ENTER A PLEA OF
- 24 GUILTY?
- THE WITNESS: YES, YOUR HONOR.

- 1 THE COURT: MR. GRACE.
- THE DEPUTY CLERK: MR. BRAUNREUTHER,
- 3 PLEASE RISE. JANSSEN PHARMACEUTICALS, INC., YOU ARE
- 4 CHARGED IN THIS INFORMATION NUMBER 13-605 CONSISTING
- 5 OF ONE COUNT, WITH INTRODUCTION OF A MISBRANDED DRUG
- 6 INTO INTERSTATE COMMERCE. HOW SAY YOU, GUILTY OR
- 7 NOT GUILTY?
- 8 THE WITNESS: ON BEHALF OF JANSSEN
- 9 PHARMACEUTICAL PURSUANT TO THE RESOLUTION AND
- 10 PURSUANT TO THE STIPULATION, I ENTER A GUILTY PLEA
- 11 ON BEHALF OF JANSSEN PHARMACEUTICA.
- 12 THE DEPUTY CLERK: THANK YOU, SIR. YOU
- 13 MAY BE SEATED.
- 14 THE COURT: DO YOU HAVE ANY QUESTIONS
- 15 ABOUT WHAT WE DID HERE?
- 16 THE WITNESS: NO, YOUR HONOR.
- 17 THE COURT: WHAT DID WE DO?
- THE WITNESS: WE JUST ENTERED A GUILTY
- 19 PLEA ON BEHALF OF THE CORPORATION JANSSEN
- 20 PHARMACEUTICA PURSUANT TO A STIPULATION REACHED WITH
- 21 THE GOVERNMENT AND AS AUTHORIZED BY A CORPORATE
- 22 RESOLUTION FROM PHARMACEUTICA -- FROM JANSSEN
- 23 PHARMACEUTICA.
- 24 THE COURT: IS EVERYTHING YOU TOLD ME
- 25 THE TRUTH?

- 1 THE WITNESS: YES, YOUR HONOR.
- THE COURT: I WILL ACCEPT THE
- 3 DEFENDANT'S PLEA OF GUILTY. I FIND AND JUDGE THE
- 4 DEFENDANT GUILTY.
- 5 IT IS MY UNDERSTANDING THAT THE PARTIES
- 6 ARE PREPARED TO PROCEED TO SENTENCING IMMEDIATELY,
- 7 AND THAT THE DEFENDANT IS WAIVING THE PREPARATION OF
- 8 A PRESENTENCE INVESTIGATION REPORT. IS THAT
- 9 CORRECT?
- MR. GLENN: YES, YOUR HONOR.
- 11 MR. SCHEFF: THAT IS CORRECT. AND YOUR
- 12 HONOR, I DO HAVE A FULLY EXECUTED WAIVER OF THE
- 13 PREPARATION OF THE PRESENTENCE REPORT SIGNED BY MR.
- 14 BRAUNREUTHER THROUGH MYSELF THAT I WOULD JUST LIKE
- 15 TO HAND UP TO THE COURT.
- 16 THE COURT: VERY WELL. I WILL HEAR YOU
- 17 ON SENTENCING.
- MR. GLENN: THANK YOU, YOUR HONOR.
- 19 YOUR HONOR, THE GOVERNMENT RECOMMENDS
- THAT THE COURT IMPOSE THE AGREED-UPON SENTENCE HERE
- 21 ON THE CORPORATION. THAT AGREED-UPON SENTENCE, YOUR
- 22 HONOR, IS A SENTENCE OF A \$334 MILLION FINE, A
- 23 \$66 MILLION FORFEITURE AND NO PROBATION. YOUR
- 24 HONOR, WE OFFER THIS AND RECOMMEND THIS AS A JUST
- 25 SENTENCE IN THIS CASE, TAKING INTO ACCOUNT THE

- 1 FACTORS UNDER 3553(A).
- THIS WOULD NORMALLY BE CALCULATED UNDER
- 3 CHAPTER 8 OF THE SENTENCING GUIDELINES, HOWEVER THE
- 4 ACTUAL CALCULATION MECHANICS IN PART C OF THAT
- 5 CHAPTER DON'T APPLY HERE BECAUSE OF THE PARTICULAR
- 6 OFFENSE AND GUIDELINES WHICH ARE INVOKED. HOWEVER,
- 7 UNDER SECTION 3553(A), YOUR HONOR, WE BELIEVE THAT
- 8 THIS IS AN APPROPRIATE SENTENCE AND A JUST SENTENCE
- 9 FOR THIS CORPORATION UNDER THESE CIRCUMSTANCES.
- 10 I WOULD NOTE A COUPLE OF FACTORS FOR
- 11 THE COURT'S CONSIDERATION UNDER SECTION 3553(A).
- 12 THE COURT HAS ALREADY AND WE HAVE ALREADY AGREED TO
- 13 THE GUIDELINE, THE ACTUAL GUIDELINE RANGE AND
- 14 CRIMINAL HISTORY. THE COMPANY IS A MAJOR
- 15 PHARMACEUTICAL MANUFACTURER. IT MANUFACTURES A
- 16 NUMBER OF PHARMACEUTICAL DRUGS WHICH BENEFIT A LARGE
- 17 NUMBER OF PATIENTS THROUGHOUT THIS COUNTRY. IT'S
- 18 BEEN IN EXISTENCE FOR OVER 40 YEARS. THE COMPANY
- 19 HAS NO CRIMINAL HISTORY. IT DOES CURRENTLY OPERATE
- 20 UNDER A CORPORATE INTEGRITY AGREEMENT RELATED TO THE
- 21 DRUG TOPAMAX, BUT THAT WAS AS A RESULT OF ITS
- 22 COMBINATION WITH ANOTHER ENTITY WHICH HAD MARKETED
- 23 TOPAMAX AT THE TIME OF THE OFFENSE WHICH RESULTED IN
- 24 THAT CORPORATE INTEGRITY AGREEMENT.
- 25 AND SO, YOUR HONOR, FOR THESE REASONS,

- 1 WE BELIEVE THAT THIS IS AN APPROPRIATE AND JUST
- 2 SENTENCE UNDER THE FACTORS UNDER SECTION 3553(A) AND
- 3 WE WOULD URGE THE COURT TO IMPOSE THE JOINTLY
- 4 RECOMMENDED AND AGREED UPON SENTENCE ON THIS
- 5 DEFENDANT.
- THE COURT: MR. SCHEFF.
- 7 MR. SCHEFF: THANK YOU, YOUR HONOR.
- 8 WE JOIN IN THE GOVERNMENT'S REQUEST AND
- 9 AGREE WITH THE GOVERNMENT'S STATEMENTS OF THE
- 10 REASONS WHY THE COURT SHOULD ACCEPT THIS AGREED-UPON
- 11 RESOLUTION OF THIS MATTER.
- 12 I WOULD NOTE ONE VERY, VERY MINOR
- 13 CORRECTION FROM WHAT THE GOVERNMENT SAID AND THAT IS
- 14 THE CORPORATE INTEGRITY AGREEMENT UNDER WHICH
- 15 JANSSEN IS OPERATING TODAY IS THE CORPORATE
- 16 INTEGRITY AGREEMENT THAT WAS NEGOTIATED IN THIS CASE
- 17 IN CONNECTION WITH THE CIVIL AGREEMENT. IT WENT
- 18 INTO EFFECT, I BELIEVE, ON MONDAY. AND SO THE OLD
- 19 AGREEMENT WHICH PERTAINED TO THE TOPAMAX MATTER HAS
- 20 BEEN SORT OF SUBSUMED INTO THIS ONE.
- 21 JANSSEN IS A COMPANY OF INNOVATION AND
- 22 RESEARCH. IT EMPLOYS THOUSANDS OF PEOPLE IN THE
- 23 UNITED STATES AND ELSEWHERE. IT DELIVERS THE
- 24 IMPORTANT HEALTH THERAPIES GLOBALLY. IT'S A GOOD
- 25 COMPANY. SO WE URGE THE COURT TO ACCEPT THIS

- 1 RESOLUTION. IT WAS NEGOTIATED OVER A LONG PERIOD OF
- 2 TIME, TAKING INTO ACCOUNT, YOU KNOW, SIGNIFICANT
- 3 DIFFERENCES IN POSITIONS THAT WE HAD AND THE RESULT
- 4 OF IMPORTANT COMPROMISE. WE DO BELIEVE IT IS A FAIR
- 5 AND JUST RESULT AS THE GOVERNMENT HAS STATED.
- THE COURT: MR. BRAUNREUTHER, IT'S YOUR
- 7 TURN TO TELL ME.
- 8 THE WITNESS: YOUR HONOR, YES, PURSUANT
- 9 TO THE RESOLUTION, AND IN PARTICULAR THE
- 10 STIPULATION, WHAT I WOULD POINT OUT IS THE COMPANY'S
- 11 EXPRESSION OF ACCEPTANCE AND REGRET. I WOULD LIKE
- 12 TO EMPHASIZE THE POINT THAT MR. SCHEFF MADE THAT
- 13 JANSSEN IS RESPONSIBLE FOR THE DELIVERY OF VALUABLE
- 14 THERAPY THAT CHANGE PEOPLE'S LIVES AROUND THE WORLD,
- 15 HAS BEEN AND REMAINS COMMITTED TO IMPROVING HUMAN
- 16 LIFE GOING FORWARD WITH ITS THERAPIES.
- 17 THE COURT: DOES IT DO THAT FROM AN
- 18 ALTRUISTIC MOTIVE OR A PROFIT MOTIVE?
- 19 THE WITNESS: I THINK --
- THE COURT: YOU CAN'T MAKE IT SOUND
- 21 LIKE THEY ARE OUT THERE DOING ALL OF THESE GOOD
- 22 WORKS AND --
- THE WITNESS: YOUR HONOR, I WOULD BE
- 24 HAPPY TO SAY THAT THERE ARE MANY PEOPLE THAT WORK
- 25 DAY IN, DAY OUT IN JANSSEN DRIVEN BY A DESIRE TO

- 1 IMPROVE PEOPLE'S LIVES AROUND THE WORLD. IT IS
- 2 ALSO, AS THE COURT POINTS OUT, A PUBLIC CORPORATION
- 3 WITH A PROFIT-MAKING INCENTIVE AS WELL.
- 4 THE COURT: IT WAS THE PROFIT MOTIVE
- 5 THAT DROVE THIS PROGRAM, DIDN'T IT?
- THE WITNESS: YOUR HONOR, I AM NOT --
- 7 AGAIN, I POINT OUT ON THE UNDERLYING FACTS, I AM
- 8 RELUCTANT TO GO BEYOND THE STIPULATION.
- 9 THE COURT: YOU DON'T HAVE TO AGREE TO
- 10 THE OBVIOUS.
- 11 THE WITNESS: THANK YOU, YOUR HONOR.
- 12 THE COURT: IN DETERMINING WHAT
- 13 SENTENCE TO IMPOSE, AND THAT IS WHETHER TO ACCEPT
- 14 THE AGREEMENT OF THE PARTIES, I TAKE INTO
- 15 CONSIDERATION ALL OF THE FACTORS SET FORTH IN 18
- 16 UNITED STATES CODE SECTION 3553(A), INCLUDING THE
- 17 NATURE AND CIRCUMSTANCES OF THE OFFENSE, AND WHAT WE
- 18 HAVE IN THIS CATEGORY IS THAT THE DEFENDANT MARKETED
- 19 A DRUG APPROVED FOR THE TREATMENT OF SCHIZOPHRENIA
- 20 TO ELDERLY PATIENTS WITH DEMENTIA AND MENTALLY
- 21 DISABLED CHILDREN WHICH WERE NOT APPROVED USES. IT
- 22 DID SO DESPITE ITS CLEAR AND UNEQUIVOCAL STUDY
- 23 SHOWING THE DRUG INCREASED THE RISK OF STROKE AND
- 24 FATALITY AMONG ELDERLY PATIENTS SUFFERING DEMENTIA.
- 25 IT DID SO IN A CALCULATED MANNER. IT WAS NOT

- 1 COINCIDENTAL NOR ACCIDENTAL. IT WAS INTENDED TO
- 2 MAXIMIZE PROFIT WITHOUT REGARD TO RISK.
- 3 THE CONDUCT THAT IT WAS ENGAGED IN
- 4 COMPROMISED THE INTEGRITY OF THE DELIVERY OF MEDICAL
- 5 SERVICES AND IT DID SO BY ENGAGING IN A PATTERN OF
- 6 KICKBACKS, BONUSES, PROVIDING SPEAKERS, PREPARING
- 7 LETTERS TO PHARMACEUTICAL DELIVERERS TO ISSUE THE
- 8 RISPERDAL PREFERRED LETTERS, AND FUNDING CONTINUING
- 9 MEDICAL EDUCATION PROGRAMS, ALL THROUGH THE IDEA OF
- 10 INCREASING THE MARKET FOR THE SALE OF THIS DRUG.
- 11 I LOOK AT THE HISTORY AND THE
- 12 CHARACTERISTICS OF THE DEFENDANT AND I SEE A LARGE
- 13 COMPANY THAT EMPLOYS INNUMERABLE PEOPLE THROUGHOUT
- 14 THE WORLD, DOES DEVELOP AS A RESULT OF ITS RESEARCH
- 15 DRUGS THAT DO HAVE A GREAT BENEFICIAL EFFECT FOR
- 16 THOSE WHO ARE PRESCRIBED THOSE DRUGS. I AM ALSO
- 17 MINDFUL THAT THE COMPANY HAS NO PRIOR CRIMINAL
- 18 HISTORY, THAT IT HAS ACCEPTED ITS RESPONSIBILITY IN
- 19 A LARGE WAY.
- 20 I CANNOT PUT ASIDE THE CIVIL SIDE OF
- 21 THIS CASE. INDEED IT WAS A GLOBAL SETTLEMENT OF ALL
- 22 ISSUES, THE CRIMINAL AND CIVIL TOGETHER. I PRESIDED
- OVER THOSE ACTIONS, KNOW WHAT WENT INTO THEM, KNOW
- 24 WHAT WORK WENT INTO THEM AND KNOW WHAT WAS GIVEN UP
- 25 AND WHAT WAS GOTTEN. I ACCEPT THE DEFENDANT'S

- 1 STATEMENT THAT IT EXPRESSES REGRET FOR WHAT HAD
- 2 HAPPENED HERE.
- 3 I ALSO LOOK AT THE NEED TO IMPOSE A
- 4 SENTENCE THAT REFLECTS THE SERIOUSNESS OF THE
- 5 OFFENSE. WHAT I SEE IS THAT THIS OFFENSE IS --
- 6 ALBEIT LABELED A MISBRANDING OF THE DRUG HAS FAR
- 7 MORE CONSEQUENCES THAN THAT OFFENSE TITLE WOULD SEEM
- 8 TO INDICATE, AND IS SURELY WHAT THE GOVERNMENT TOOK
- 9 INTO CONSIDERATION WHEN IT ENTERED INTO THIS
- 10 AGREEMENT. AND THAT IS THAT IT COMPROMISED THE
- 11 INTEGRITY OF THE DELIVERY OF MEDICAL SERVICES AND
- 12 HAS HAD A TENDENCY TO CORRUPT THE DECISIONS MADE BY
- 13 PHYSICIANS WHO ARE OUT IN THE FIELD PRESCRIBING
- 14 THESE MEDICATIONS.
- 15 I LOOK AT THE NEED TO PROMOTE RESPECT
- 16 FOR THE LAW. THIS AGREEMENT APPEARS TO SATISFY THAT
- 17 FACTOR. I LOOK AT THE NEED TO AFFORD DETERRENCE AND
- 18 WHAT YOU HAVE IN THIS CASE IS THAT PHARMACEUTICAL
- 19 COMPANY IS GOING TO KNOW THERE IS GOING TO BE A COST
- 20 TO PAY, IT GOES BEYOND MONEY. IT'S GOING TO TARNISH
- 21 THE REPUTATION OF THE COMPANY, WHICH NOW HAS A
- 22 CRIMINAL RECORD. THE CIVIL SETTLEMENT IS SOMEWHAT
- 23 LARGE. THAT IS A DETERRENT EFFECT.
- 24 WHEN I LOOK AT THE NEED TO PROTECT THE
- 25 PUBLIC FROM THE DEFENDANT'S FURTHER CRIMES, WE HAVE

- 1 HERE A CORPORATE INTEGRITY AGREEMENT. THIS COMPANY
- 2 IS GOING TO BE UNDER A MAGNIFYING GLASS FOR A PERIOD
- 3 OF TIME. IT'S GOING TO HAVE TO COMPLY AND SUBMIT
- 4 COMPLIANCE REPORTS TO THE DEPARTMENT OF HEALTH AND
- 5 HUMAN SERVICES. THAT'S A PRICE TO PAY. NO COMPANY
- 6 OPERATING WANTS TO HAVE THE GOVERNMENT OVER ITS
- 7 SHOULDER. IT'S NO LONGER GOING TO BE OFFERING THIS
- 8 DRUG OR ANY SIMILAR DRUGS OFF LABEL.
- 9 I LOOK AT THE KINDS OF SENTENCES
- 10 AVAILABLE AND THE SENTENCING RANGE THAT IS PROVIDED
- 11 FOR IN THE SENTENCING GUIDELINES. THIS PARTICULAR
- 12 AGREED-UPON SENTENCE FAR EXCEEDS WHAT COULD BE
- 13 IMPOSED IN TERMS OF THE GUIDELINES. THERE REALLY IS
- 14 NO BAROMETER TO JUDGE THE FACTOR OF THE NEED TO
- 15 AVOID UNWARRANTED SENTENCE DISPARITIES AMONG
- 16 DEFENDANTS WITH SIMILAR -- RECOGNIZING WHO HAVE BEEN
- 17 FOUND GUILTY OF SIMILAR CONDUCT. WE JUST DON'T HAVE
- 18 A BENCHMARK IN THIS CASE.
- 19 FOR ALL OF THOSE REASONS, IT IS THE
- 20 JUDGMENT OF THE COURT THAT THE DEFENDANT SHALL PAY
- 21 TO THE UNITED STATES A SPECIAL ASSESSMENT OF \$125
- 22 WHICH SHALL BE DUE IMMEDIATELY. THE DEFENDANT SHALL
- 23 PAY A FINE IN THE AMOUNT OF \$334 MILLION WITHIN 10
- 24 BUSINESS DAYS. I WILL GRANT THE GOVERNMENT'S MOTION
- 25 FOR FORFEITURE AND THE DEFENDANT IS ORDERED TO PAY

- 1 \$66 MILLION IN SUBSTITUTE ASSETS TO SATISFY THAT
- 2 FORFEITURE. THE TOTAL PAYMENT PURSUANT TO THE
- 3 SETTLEMENT AGREEMENT AND THIS GUILTY PLEA IS
- 4 \$400 MILLION.
- 5 ANYTHING ELSE ON THE SENTENCE,
- 6 GENTLEMEN?
- 7 MR. GLENN: JUST TO NOTE THAT THERE
- 8 WILL BE NO PROBATION IMPOSED.
- 9 THE COURT: THERE IS NONE. I DIDN'T
- 10 ORDER IT.
- MR. GLENN: THANK YOU, YOUR HONOR.
- MR. SCHEFF: YOUR HONOR, I HAVE NO
- 13 COMMENT ON THE SENTENCE THAT THE COURT HAS IMPOSED.
- 14 I JUST WANT THE RECORD TO REFLECT THAT NUMBER ONE,
- THIS IS A MISDEMEANOR OFFENSE, WHICH I DON'T THINK
- 16 HAS BEEN STATED BEFORE ON THE RECORD, AND ALSO TO
- 17 SAY THAT THE COMPANY'S ADMISSION WITH RESPECT TO THE
- 18 CONDUCT AT ISSUE IS LIMITED TO WHAT IS IN PARAGRAPH
- 19 8 OF THE PLEA AGREEMENT WHICH MR. GLENN READ INTO
- 20 THE RECORD AND MR. BRAUNREUTHER ACKNOWLEDGED
- 21 PURSUANT TO THE AUTHORIZATION HE HAS FROM THE
- 22 COMPANY. THE COMMENTS THAT THE COURT MADE ABOUT
- 23 ALLEGATIONS THAT HAVE BEEN MADE ARE NOT THINGS THAT
- 24 THE COMPANY ACCEPTS, RATHER THE COMPANY DISPUTES.
- 25 AND I THINK IT IS IMPORTANT THAT THE RECORD REFLECT

- 1 THAT.
- THE COURT: YOUR STATEMENT IS ON THE
- 3 RECORD AS YOU STATED IT.
- 4 MR. SCHEFF: THANK YOU, SIR.
- 5 THE COURT: I AM NOT SUGGESTING I AM
- 6 ADOPTING IT.
- 7 MR. SCHEFF: I UNDERSTAND.
- 8 THE COURT: YOU UNDERSTAND THAT YOU
- 9 GAVE UP YOUR RIGHT TO APPEAL?
- 10 THE WITNESS: YES, YOUR HONOR.
- 11 THE COURT: IN ANY EVENT, GIVE HIM HIS
- 12 RIGHT TO APPEAL.
- 13 MR. SCHEFF: THE COMPANY HAS THE RIGHT
- 14 TO FILE AN APPEAL WITHIN 10 DAYS BY FILING A NOTICE
- 15 -- WITHIN 14 DAYS BY FILING A NOTICE HERE WITH THE
- 16 DISTRICT COURT AND WITH THE COURT OF APPEALS. IT
- 17 NEEDS TO BE A SIMPLE STATEMENT OF APPEAL FROM THE
- JUDGMENT AND COMMITMENT ORDER ENTERED BY THE COURT
- 19 TODAY.
- 20 THE COURT: ALL RIGHT. I MUST MAKE
- 21 THIS OBSERVATION. HAVING BEEN FOR THE PAST SEVERAL
- 22 YEARS OVERSEEING THE CIVIL END OF THIS AND THIS
- 23 CRIMINAL PROCEEDING, I CAN'T HELP BUT OBSERVE THAT
- 24 THE RESULT WHICH IS IN THE PUBLIC INTEREST COULD NOT
- 25 HAVE BEEN ACCOMPLISHED WITHOUT THE EXPERTISE, THE

1	PATIENCE AND THE PROFESSIONALISM OF THE LAWYERS IN
2	BOTH THE CIVIL AND CRIMINAL DIVISIONS IN THE UNITED
3	STATES ATTORNEY'S OFFICE FOR THE EASTERN DISTRICT OF
4	PENNSYLVANIA.
5	ANYTHING ELSE?
6	MR. SCHEFF: NO, YOUR HONOR.
7	MR. GLENN: NO. THANK YOU, YOUR HONOR.
8	(ALL RISE.)
9	(COURT ADJOURNED.)
10	
11	
12	
13	I CERTIFY THAT THE FOREGOING IS A
14	CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN
15	THE ABOVE-ENTITLED MATTER.
16	
17	
18	
19	DATE OFFICIAL COURT REPORTER
20	LYNN MCCLOSKEY, RPR
21	
22	
23	
24	
25	

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